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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,148	12/02/2003	Koji Yoshimura	PF613TD1	4267

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EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,148	YOSHIMURA ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 37-57* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/786,256.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's response to restriction requirement filed 5/26/2004 is acknowledged. Applicant elected Group III invention, represented by new claims 37-57, drawn to ADAM polypeptides corresponding to SEQ ID NO:15 with traverse. Claims 1-18, 20-36 are canceled. Claim 19 is withdrawn as drawn to non-elected invention.

In traversal of restriction requirement applicant argues the following: that **firstly** the office has erred in assuming that this application is a national stage entry of an International application under, 35 U.S.C. section 371, and in fact, this case is a divisional of such filing and should have been restricted according to 35 U.S.C. section 121. Further the preliminary amendment filed 12/02/2003 should have been considered before drafting the restriction letter.

Secondly, in response to Examiner's indication that the inventions of Groups I-XII are patentably distinct as they are directed to products of unrelated chemical structure and function applicant argues that said supposedly patentably distinct inventions are indeed related and exhibit substantial similarity as disclosed in the specification. Thus, according to applicant, a search of the claims of any of the groups would also provide useful information for the claims of other groups. The Office has not established that the search and examination of all groups would entail a "serious burden" and therefore, restriction as indicated in the previous office action, is improper.

Thirdly, even if the Examiner's restriction of the instant invention under 35 U.S.C. section 372 were proper, many of the Groups are linked so as to form a single general inventive concept under PCT Rule 13.1, and thus should be examined together

or at the very least, the polypeptides of Group I and III , which share the sequence of the polypeptides of Group II as a single general inventive concept should be rejoined.

Applicant finally concludes that in view of the arguments provided above, the restriction requirement under 35 U.S.C. section 121 or section 372 is improper and should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. In response to applicant's **first** argument the examiner agrees that this case is not a national stage entry of an international application and should have been restricted under 35 U.S. section 121 after considering the preliminary amendment of 12/02/2003. The Examiner apologizes for said inadvertent error.

With respect to applicant's **second** argument the examiner again agrees with the applicant that the search of the claims of some Groups, as indicated in the previous office action, may provide some useful information for the claims of other groups. However, the searches of groups I-XII are **not coextensive.** For example, the search for antibody inventions (see Groups V and VI in the previous office action) requires a search in class 530/387.1, which is totally irrelevant to inventions of Groups I-III or IX-XI and XII. Similarly, the search for Groups III-IV requires a search in class 530/350 which is not required to be searched for invention of Groups I, V-VI or X etc. Thus, in contrast to applicant's view, rejoinder of all inventions **does impose an undue burden** of searching on the examiner.

Finally, in view of the case being a regular U.S. case and not a national stage entry of an international application, as applicant himself/herself indicated, applicant's

third arguments regarding inventions of Groups I-II forming a single general invention concept etc,. are irrelevant.

In conclusion, in view of the response provided above, in addition to reasons provided in the previous office action, restriction is maintained under 35 U.S.C. section 121 and is hereby made **final**.

DETAILED ACTION

Claims 37-57 are under examination on the merits. Claims 1-18 and 20-36 are canceled. Claim 19 is withdrawn as drawn to non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 37 and 39 are directed to a **genus** of polypeptides comprising merely residues 428-437 of SEQ ID NO:15 which are not adequately described in the specification.

SEQ ID NO:15 is disclosed to have 775 amino acids, encoding a protease.

The specification does not provide any teachings about what the other amino acid constituents of claimed polypeptides (see claims 37(b) and 39) beyond those

corresponding to amino acids 428-437 of SEQ ID NO:15 must be and how they should be organized such that they can form a three dimensional structure capable of having protease activity. Applicant merely provides a **single species** (namely SEQ ID NO:15) describing the genus so broadly claimed, which is insufficient to put applicant in possession of all members of the genus.

Since claim 37 lacks adequate written description its dependent claims 38, 40-46 also lack adequate written description.

With respect to claims 47-57 it should be noted that here, applicant (see claims 47, 51-52) is claiming a **genus** of SEQ ID NO:15 variants having at least 90% identity to SEQ ID NO:15, which are merely described by structure. No functional description of claimed polypeptides has been provided of the homologous sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:15 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. Applicant is well aware that many polypeptides of similar amino acid composition may have entirely unrelated functions. The specification does not contain any disclosure of the function of all the variant polypeptide sequences derived from SEQ ID NO:15, that are within the scope of the claimed genus. Therefore many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a **single species** (SEQ ID NO:15) of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in

the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Since the polypeptides of claim 47 are inadequately described the polypeptides of claims 48-57 which depend from claim 47 are inadequately described as well.

With respect to claim 47, it should additionally be noted that the examiner searched the entire specification in support of the term "90% or more identical to SEQ ID NO:15" and could not find any. Hence, for examination purposes said term is considered to be **new matter**. Applicant is advised to either direct the Examiner to the part of the specification wherein said term has been explicitly disclosed or possibly delete said term from claim 47. Claims 48-57 are rejected merely for depending from the rejected base claim 47.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 37-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein comprising amino acid residues 1-775 of SEQ ID NO:15 , does not reasonably provide enablement for an isolated protein comprising amino acids 428-437 of SEQ ID NO:15, or isolated polypeptides comprising an amino acid fragment 90% or more identical to residues 1-775 of SEQ ID NO:15 with no associated protease activity.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount

of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which residues other than those corresponding to residues 428-437 of SEQ ID NO:15 must be incorporated in polypeptides of claim 37(b) and claim 39 such that they will be able to retain the appropriate three dimensional structure for protease activity. No examples of such polypeptides or residues within such polypeptides are provided either. Current state of the prior art indicates that 437-428=9 polypeptides are totally incapable of retaining any function.

Therefore due to lack of sufficient and teachings provided in the specification and due to unpredictability of prior art as to which residues must be imported in polypeptides of claims 37 and 39 such that they retain protease activity one of skill in the art has to go through the burden of undue experimentation in order to screen for polypeptides that are within the scope of this specification.

Claims 38, 40-47 are merely rejected for depending from rejected claim 37.

With respect to polypeptides of claim 47-52 it should be noted that the specification again fails to teach which critical residues within the claimed SEQ ID NO:15 variants are in charge of assigning function to said products. No examples of such residues are provided either. Current state of the prior art indicates that any polypeptide which happens to have at least 90% identity to that encoding a full-length polypeptide is not necessarily capable of retaining the activity of said full-length polypeptide.

Therefore due to lack of sufficient teachings and examples provided in the specification and due to unpredictability of prior art as to which critical residues within claimed variants must be retained such that said variants could retain protease activity one of skill in the art has to go through the burden of undue experimentation in order to screen for thus variants that have protease activity and are therefore within the scope of the disclosure.

Claims 53-57 are rejected merely for depending from rejected base claim 47.

Claims 37-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 37, 40, 41, and 47, 49, 50 are rejected for not being in compliance with deposit requirement rules.

It is noted that the applicants have deposited the organisms but there is no indication in the specification as to the public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to

certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application, access to the invention will be afforded to the commissioner upon request;

2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent whichever is longer; and

4. the deposit will be replaced if it should ever become inviable.

Claims 38-39, 42-46 are rejected for depending from rejected base claim 37. similarly claims 48, 51-57 are rejected for depending from the rejected base claim 47.

No claims are allowed.

Allowable subject matter

SEQ ID NO:15 and its homologs of at least 95% identity or higher to said amino acid sequence with protease activity are allowable because SEQ ID NO:15 and its mentioned variants with protease activity are free of prior art. Further, the prior art does not teach or suggest preparing such specifically claimed amino acid sequences with protease activity. Hence, said amino acid sequences are also non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maryam Monshipouri Ph.D.

Primary Examiner

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